

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: *Toranto et al.*  
Serial No.: 09/976,872  
Filed: 10/12/2001  
Entitled: **ANALYTE DETECTION**

Confirmation: 2860  
Group No.: 1641  
Examiner: Cook

**DECLARATION OF EVAN SINGER  
UNDER 37 CFR § 1.132**

EFS Web filed  
Commissioner for Patents  
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<b>CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8</b>	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being transmitted to the United States Patent and Trademark Office transmitted via the Office electronic filing system in accordance with 37 C.F.R. §1.6(a)(4).	
Dated: <u>August 17, 2009</u>	By: <u>/Michele R. Gilmer/</u> Michele R. Gilmer

Dear Examiner Cook:

I, Evan Singer, hereby declare and state, under penalty of perjury, that:

1. I am one of the inventors of the above-named patent application (hereafter; present application).
2. Many of the costs, risks, and penalties associated with alcohol-related accidents could be prevented if individual alcohol consumers were capable of making a self-assessment of their capacity to engage in potentially dangerous activities.
3. The invention meets the need of individual alcohol consumers to self assess their ability to operate a motor vehicle or engage in other potentially dangerous activities. The

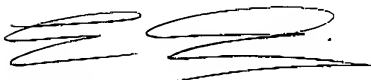
invention meets this need by providing low cost, non-toxic, stable, easy to use, quantitative, colorimetric alcohol testing methods. These tests can be contained in a simple strip that is inserted into the mouth without the need to transfer saliva to a separate reaction chamber. This user friendliness increases the chance that consumers will use these valuable, and potentially lifesaving tests.

4. Making such a user-friendly test presented a number of significant challenges. Among these challenges, we needed to find a detection chemistry that simultaneously was: 1) non-toxic (so that it could be placed into the mouth); 2) sensitive enough to detect low levels of alcohol; 3) able to reproducibly provide a detectable visible color; 4) provide a quantitative or semi-quantitative result; 5) provide "on/off" detection at particular alcohol levels; 6) not be triggered by other saliva components; and 7) be sufficiently durable to survive manufacture, shipping, and handling by customers. We were not sure whether any such chemistry existed.

5. The menu of possible chemistries was non-trivial. There were a variety of different enzyme systems, including alcohol oxidase and dehydrogenase and numerous chromagens that could be mixed and matched with different enzyme systems.

6. In order to arrive at the methods of the presently claimed invention, a large amount of experimentation was required. After much experimentation, potassium iodide, in combination with enzyme systems, was found to provide a non-toxic, stable, detectable, quantitative, on/off colorimetric chromagen that met all of the criteria we needed. No other tested chromagens worked sufficiently. If we had not discovered this successful combination, it is unclear whether any other option would have been possible. The various chromagens used in the prior art did not work for one reason or another: too toxic, not sensitive enough, too high a level of false positives or false negatives. It cannot be said that any chromagens that function with alcohol dehydrogenase (the enzyme system we settled on) are interchangeable with one another. Our experiments, and those of others demonstrated that the opposite is true: The potassium iodide was the needle in the haystack; most (and perhaps all) other chromagens are unsuitable in meeting all of the criteria for the user friendly test we sought to design.

7. I declare that all statements made herein are of my own knowledge and are true, and further that those statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the patent application or any patent issuing there from.



Evan Singer

Aug 17, 2009

Date